DEC - 3 1999

K993708

SECTION 11

510(k) SUMMARY

BIOMAGNETIC TECHNOLOGIES, INC
MAGNES® 3600 WHOLE HEAD MEG

This 510(k) summary of safety and effectiveness for the Magnes® 3600 WH MEG is submitted in accordance with the requirements of SMDA 1990 and follows guidance from the Office of Device Evaluation concerning the organization and content of a 510(k) summary.

Applicant:	Biomagnetic Technologies, Inc. 9727 Pacific Heights Blvd. San Diego, CA 92121-3719
Address (Manufacturer):	Biomagnetic Technologies, Inc. 9727 Pacific Heights Blvd. San Diego, CA 92121-3791
Contact Person:	Eugene C. Hirschkoff, Ph.D. Vice President, Engineering (619) 458-5617
Telephone:	(619) 453-6300 (619) 453-4913 (Fax)
Preparation Date:	October 1999
Device Trade Name:	Magnes® 3600 Whole Head Magnetoencephalograph (MEG)
Common Name:	Electroencephalograph; biomagnetometer
Classification Name:	Electroencephalograph
Class:	Class II
Legally marketed predicate device:	Magnes® 2500 WH MEG
Description of Device:	The Magnes® 3600 WH MEG consists of a magnetic sensor for detecting and measuring magnetic fields produced by the human brain, along with auxiliary equipment required to perform the measurements in a conventional medical facility environment and to display the results of the measurements to physicians in a variety of ways.

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Intended Use:	The Magnes®3600 WH MEG is intended for use in diagnostic procedures that require the measurement and display of extracranial magnetic fields and information about the electrical activity in the brain as inferred from those fields.
Performance Data:	Because the specifications, performance characteristics, and intended uses of the Magnes® 3600 WH MEG are the same as the Magnes® 2500 WH MEG no performance data were required.
CONCLUSION:	Based on the foregoing, Biomagnetic Technologies, Inc., believes that the Magnes® 3600 WH MEG is substantially equivalent to the Magnes® 2500 WH MEG.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 1999

Eugene C. Hirschkoff, Ph.D.
Vice President, Engineering
Biomagnetic Technologies, Inc.
9727 Pacific Heights Boulevard
San Diego, California 92121

Re: K993708
Trade Name: Magnes® 3600 Whole Head Magnetic Encephalograph
Regulatory Class: II
Product Code: GWQ
Dated: November 2, 1999
Received: November 3, 1999

Dear Dr. Hirschkoff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K993708

Device Name: Magnes® 3600 Whole Head (WH) Magnetic Encephalograph (MEG)

Indications for Use Statement:

The Magnes®3600 WH MEG is intended for use in diagnostic procedures that require the measurement and display of extracranial magnetic fields and information about the electrical activity in the brain as inferred from those fields.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The Counter Use ___
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993708

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